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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,643	02/10/2000	Dr. Larry Sklar	UNME-0070-1	4170

7590 09/23/2003
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EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/501,643

Applicant(s)

SKLAR ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-27,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-27,46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 5/8/03, in Paper No. 19 is acknowledged and has been entered. Amendment to the specification has been entered. Claims 1-7, 9-27, 46, and 47 are pending and are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. In light of Applicant's argument, the rejection of claims 1-7, 9-27, 46, and 47 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1-7, 9-27, 46, and 47 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of parameter controlled separation gas in a compatible flow cytometric device, does not reasonably provide enablement for use of any separation gas introduced into any flow cytometric device. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection has been maintained for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-3, 5, 7, 9-12, 15-19, and 26-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Saros et al. (US 4,853,336) in view of Weigl et al. (US 6,159,739) for reasons of record.

5. Claims 4, 6, 13-14, 20-24, 46, and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Saros et al. (US 4,853,336) in view of Weigl et al. (US 6,159,739) as applied to claims 1-3, 5, 7, 9-12, 15-19, and 26-27 above, and further in view of Kercso et al. (US 6,132,685) for reasons of record.

6. Claim 25 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Saros et al. (US 4,853,336) in view of Weigl et al. (US 6,159,739) as applied to claims 1-3, 5, 7, 9-12, 15-19, and 26-27 above, further in view of Kercso et al. (US 6,132,685), and in further view of Farrell et al. (US 5,788,927) for reasons of record.

Response to Arguments

7. Applicant's arguments filed 5/8/03 have been fully considered but they are not persuasive.

A) Applicant contends that the specification has described the subject matter in such a way as to convey to one reasonable skill in the art that at the time that the application was filed that Applicant had possession of the claimed invention and points throughout the specification for support.

In response, the Applicant's argument is not on point. The rejection is based on scope of enablement issue rather than lack of written description in the specification. Specifically, the claims were rejected under 35 U.S.C. 112, first paragraph, because the

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specification, while being enabled for a flow cytometry apparatus having parameter controlled separation gas, by virtue of specific sized tubing in congruent with limited specified speeds, in a compatible flow cytometric analytical device, does not reasonably provide enablement for any flow cytometry apparatus having parts and functions with unlimited parametric requirements.

B) Applicant contends that considerable guidance was provided in Applicant's disclosure in as far as which type of gas and type of flow cytometry apparatus are suitable for use in the claimed flow cytometry apparatus and that for those reasons, claim 1 should be enabled.

Applicant's argument is not on point. The enablement issue points toward parametric requirements in the parts, i.e. tubings and functions, i.e. flow rates, of the flow cytometry apparatus, that create separation gas, that renders it functional with the concept of flow cytometry. The specification provides that peristaltic flow rates of +/-3 ul /second through common tubing (0.02 inch tubing, 10 rpm or higher) are parameters that are compatible with flow cytometry because of the requirement for hydrodynamic focusing in flow cytometric type detection. The claims, however, are not limited to these requirements. As recited, the instant flow cytometry apparatus for hydrodynamic focusing of fluid flow streams can function to selectively analyze particles in a plurality of samples separated by a separation gas regardless of the tubing size, amount of gas introduced, or fluid flow rates introduced into the device. Applicant's disclosure however states that in flow cytometry, there is specific teaching in the art against the presence of

gas in fluid flow streams and that optimally, gas should be removed from or refrained from introduction into tubings. The specification, thus, fails to provide any guidance to enable a standard flow cytometry apparatus to function with any size of tubing, any flow rate, or any amount of separation gas introduced into standard fluid flow stream tubing to separate individual samples, so as to be commensurate in scope with claim 1.

C) Applicant concurs with Examiner's statement that the prior art of records fail to disclose a flow cytometry apparatus for hydrodynamic focusing of flow streams for analysis of particles in a plurality of samples which are separated by a separation gas. Applicant then argues that the rejection of the claimed invention based on the combination of Saros with Weigl and also in further view of Kercso and Farrell, should be withdrawn, based on such assessment.

In response, indeed, prior art of record fails to teach "a flow cytometer for hydrodynamically focusing the fluid flow stream and *selectively analyzing said particles ... as the flow stream passes through the flow cytometer*".

In as far the prior art rejection based on the combination of Saros with Weigl and also in further view of Kercso and Farrell, the rejection is based on the use of "comprising" language in claim 1. Use of "comprising" language does not exclude the combined teaching or embodiment taught by Saros and Weigl and in combination with Kercso and Farrel. Specifically, Saros discloses a flow system comprising an autosampler for moving a plurality of samples, a means for introducing a separation gas between each sample, and the tubing for passage of fluid stream therethrough. The

walls of the tubing have an expanded diameter sufficient to render the separation gas, non-occluding. Weigl is combined therewith, for the disclosure of a (separate) flow module for performing analytical measurement and wherein particles are reproducibly focused in a measurement zone of the flow cytometer, and wherein selective analysis of particles in a plurality of samples takes place. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Accordingly, the prior art rejections have been maintained.

8. For reasons aforementioned, no claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641

September 11, 2003 *g*



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641